K131012

APPLICANT: SUTTER MEDIZINTECHNIK GMBH
DEVICES: SUTTER BIPOLAR FORCEPS - SUPERGLISS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Section 807.92(c)

Date: *807.92(a)(1)*	August 20, 2013	
Submitter: *807.92(a)(1)*	Name: Address: Managing Director: Telephone: Fax: Contact person: Telephone: E-mail:	SUTTER MEDIZINTECHNIK GmbH Tullastrasse 87 79108 Freiburg Germany Bert Sutter +49 (0) 761 51551-0 +49 (0) 761 51551-30 Dr. Sabine Klugbauer +49 (0) 761 51551-14 klugbauer@sutter-med.de
Product: *807.92(a)(2)*	Trade Name: Classification: Common Name: Product Code and Classification Name:	Sutter Bipolar Forceps - SuperGliss Class II; CFR 21 § 878.4400 Electrosurgical Instruments and Accessories GEI - Electrosurgical Cutting & Coagulation Device & Accessories
Predicate Device: *807.92(a)(3)*	Predicate devices to which Sutter Bipolar Forceps SuperGliss are claimed to be substantially equivalent are manufactured by • Egon Faulhaber Surgical Instruments Pinzetten, Bipolar, Nonstick bipolar forceps (K101080) • Guenter Bissinger, Claris Non-Stick Bipolar Forceps (K051429)	
Device Description: *807.92(a)(4)*	Sutter Bipolar Forceps – SuperGliss is an electrosurgical tool in tweezers configuration with differences in tip size and branches styles. It is constructed with medical grade stainless steel (branches), coated with Polyamid PA 11 as electrical insulator and possesses a tip made of silver alloy that is not insulated. The forceps can be connected through an appropriate bipolar cable with the bipolar output of an electrosurgical generator. As an electrosurgical accessory it is designed to grasp, manipulate and coagulate selected tissue. The maximum peak voltage to use the forceps is 500 Vp. The forceps are provided non-sterile, are reusable and must be sterilized prior initial and subsequent use.	
Intended Use: *807.92(a)(5)*	Intended Use: Sutter Bipolar Forceps SuperGliss are designed to grasp, manipulate and coagulate selected tissue. They are to be connected to the bipolar output of an electrosurgical generator with an appropriate bipolar cable and must only be used with parameters for bipolar coagulation. Indications: General surgery, Orthopaedic coagulation, Thoracic coagulation, Neurosurgical coagulation, Gynaecological coagulation (except for use in female sterilisation), Urological coagulation, Ear-,	

AUG 2 3 2013

APPLICANT: SUTTER MEDIZINTECHNIK GMBH
DEVICES: SUTTER BIPOLAR FORCEPS - SUPERGLISS

<table>
<tr><td></td><td>Nose- and Throat coagulation.
Contraindications: Sutter Bipolar Forceps SuperGliss have not been shown to be effective for tubal sterilisation or tubal coagulation for sterilisation procedures and should not be used for this purpose.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Performance Testing:
807.92(b)(1)</td><td>Non-clinical laboratory performance testing was done on different types of meat with determination of coagulation areas for various tip sizes and statistical analysis of the results. Bench testing according to standards series IEC 60601 has also been performed.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Substantial Equivalence:
807.92(b)(3)</td><td>Comparison of Basic Features, design, testing results and intended uses show that Sutter Bipolar Forceps SuperGliss are substantial equivalent to the predicate devices.
<table>
<tr><th>Feature</th><th>Sutter SuperGliss</th><th>Predicate devices K101080/K051429</th></tr>
<tr><td>Intended Use</td><td>As shown above under Intended Use</td><td>Same/Same</td></tr>
<tr><td>Branches Style</td><td>Straight, angled, bayonet</td><td>Same/Same</td></tr>
<tr><td>Dimensions
Length [mm]:
Tip size [mm]:</td><td>
110 – 280
0.2 – 2.5</td><td>
110 – 250 / 110 – 240
0.25 – 2.0 / 0.25 – 2.0</td></tr>
<tr><td>Material Tips:
Coating:
Connector:
Branches:</td><td>Silver Alloy
Polyamide (PA) 11
Stainless steel/PEEK
Stainless steel</td><td>Same/Same</td></tr>
<tr><td>Bipolar</td><td>yes</td><td>Same/Same</td></tr>
<tr><td>Meets IEC 60601-2-2</td><td>yes</td><td>Same/Same</td></tr>
<tr><td>Maximum peak voltage</td><td>500 Vp</td><td>Same/Same</td></tr>
<tr><td>Sterility</td><td>Non-sterile, reusable</td><td>Same/Same</td></tr>
<tr><td>Sterilization method</td><td>Steam-sterilisation by user</td><td>Same/Same</td></tr>
</table>
</td></tr>
</table>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sutter Medizintechnik GmbH
% Dr. Sabine Klugbauer
Manager, Regulatory Affairs
Tullastrasse 87
79108 Freiburg, Germany

August 23, 2013

Re: K131012
Trade/Device Name: Sutter Bipolar Forceps - SuperGliss
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 3, 2013
Received: July 12, 2013

Dear Dr. Klugbauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICANT: SUTTER MEDIZINTECHNIK GMBH
DEVICES: SUTTER BIPOLAR FORCEPS - SUPERGLISS

Indications for Use Form

Indications for Use

510(k) Number (if known): K131012

Device Name: Sutter Bipolar Forceps - SuperGliss

Indications for Use:

Intended Use:

Sutter Bipolar Forceps SuperGliss are designed to grasp, manipulate and coagulate selected tissue. They are to be connected to the bipolar output of an electrosurgical generator with an appropriate bipolar cable and must only be used with parameters for bipolar coagulation.

Indications:

General surgery, Orthopaedic coagulation, Thoracic coagulation, Neurosurgical coagulation, Gynaecological coagulation (except for use in female sterilisation), Urological coagulation, Ear-, Nose- and Throat coagulation.

Contraindications:

Sutter Bipolar Forceps SuperGliss have not been shown to be effective for tubal sterilisation or tubal coagulation for sterilisation procedures and should not be used for this purpose.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off
Division of Surgical Devices
510(k) Number: K131012

Joshua C. Nipper -S